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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,099	06/08/2007	Takeshi Matsui	082368-010000US	4338
20350 7590 11/12/2008 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER ALLEN, MARIANNE P	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 11/12/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,099	<b>Applicant(s)</b> MATSUI ET AL.	
	<b>Examiner</b> Marianne P. Allen	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8 is/are rejected.
- 7) ☒ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/1/07, 6/8/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Claims 5-6 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can only depend on claims in the alternative and cannot depend from another multiply dependent claim. See MPEP § 608.01(n). Accordingly, the claims 5-6 have not been further treated on the merits.

### ***Election/Restrictions***

Claims 7 and 9-20 have been cancelled. Applicant elected claims 1-6 and 8 and SEQ ID NOS: 7-8 without traverse and has amended the claims to reflect the elected invention.

### ***Specification***

The substitute specification filed 8/29/06 has been entered.

The specification does not reference the sequence identifiers that correspond to the sequences disclosed in Figure 2C and Figure 4A. See the figures and brief description of the figures. Correction is required.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims do not evidence the hand of man (e.g. reciting isolated, purified products) and encompass a product of nature.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Valenzuela et al. (WO 99/55721).

Valenzuela et al. discloses SEQ ID NOS: 53 (1897 nucleotides) and 54 (479 amino acids). Probes and vectors are disclosed. SEQ ID NO: 53 of Valenzuela et al. has 92% identity to instant SEQ ID NO: 7 and SEQ ID NO: 54 of Valenzuela et al. has 96% identity to SEQ ID NO: 8. (See pages 85-88; pages 137-138; claims 62-63; and sequence alignment below.) Absent evidence to the contrary and in view of the high structural similarity, the polynucleotide and amino acid sequences of Valenzuela et al. would inherently possess the properties recited in claim 1 parts (c) and (d) and claim 2. Evidence that these properties are not possessed by the sequences of Valenzuela et al. will be viewed as evidence that the claims are not enabled for the breadth of the polynucleotides encompassed.

Sequence 1897 BP

Query Match

91.6%; Score 1816.2; DB 3; Length 1897;

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Best Local Similarity 97.8%; Pred. No. 0;  
Matches 1855; Conservative 0; Mismatches 33; Indels 9; Gaps 1;

```
Qy      85 ACAGAGGAGGGCACAGAGACGCAGAGCAAGGGCGGCAAGGAGGAGACCCTGGTGGGAGGA 144
      |||
Db      1 ACAGAGGAGGGCACAGAGACGCAGAGCAAGGGCGGCAAGGAGGAGACCCTGGTGGGAGGA 60

Qy     145 AGACACTCTGGAGAGAGAGGGGGCTGGGCAGAGATGAAGTTCCAGGGGCCCCCTGGCCTGC 204
      |||
Db      61 AGACACTCTGGAGAGAGAGGGGGCTGGGCAGAGATGAAGTTCCAGGGGCCCCCTGGCCTGC 120

Qy     205 CTCCTGCTGGCCCTCTGCCTGGGCAGTGGGGAGGCTGGCCCCCTGCAGAGCGGAGAGGAA 264
      |||
Db     121 CTCCTGCTGGCCCTCTGCCTGGGCAGTGGGGAGGCTGGCCCCCTGCAGAGCGGAGAGGAA 180

Qy     265 AGCACTGGGACAAATATTGGGGAGGCCCTTGACATGGCCTGGGAGACGCCCTGAGCGAA 324
      |||
Db     181 AGCACTGGGACAAATATTGGGGAGGCCCTTGACATGGCCTGGGAGACGCCCTGAGCGAA 240

Qy     325 GGGGTGGGAAAGGCCATTGGCAAAGAGGCCGGAGGGGCAGCTGGCTCTAAAGTCAGTGAG 384
      |||
Db     241 GGGGTGGGAAAGGCCATTGGCAAAGAGGCCGGAGGGGCAGCTGGCTCTAAAGTCAGTGAG 300

Qy     385 GCCCTTGGCCAAGGGACCAGAGAAGCAGTTGGCACTGGAGTCAGGCAGGTTCCAGGCTTT 444
      |||
Db     301 GCCCTTGGCCAAGGGACCAGAGAAGCAGTTGGCACTGGAGTCAGGCAGGTTCCAGGCTTT 360

Qy     445 GGCGCAGCAGATGCTTTGGGCAACAGGGTCGGGGAAGCAGCCCATGCTCTGGGAAACACT 504
      |||
Db     361 GGCGTAGCAGATGCTTTGGGCAACAGGGTCGGGGAAGCAGCCCATGCTCTGGGAAACACT 420

Qy     505 GGGCAGCAGATTGGCAGACAGGCAGAAGATGTCATTCGACACGGAGCAGATGCTGTCCGC 564
      |||
Db     421 GGGCAGCAGATTGGCAGACAGGCAGAAGATGTCATTCGACACGGAGCAGATGCTGTCCGC 480

Qy     565 GGCTCCTGGCAGGGGGTGCCTGGCCACAATGGTGCTTGGGAAACTTCTGGAGGCCATGGC 624
      |||
Db     481 GGCTCCTGGCAGGGGGTGCCTGGCCACAATGGTGCTTGGGAAACTTCTGGAGGCCATGGC 540

Qy     625 ATCTTTGGCTCTCAAGGTGGCCTTGAGAGGCCAGGGCCAGGGCAATCCTGGAGGTCTGGGG 684
      |||
Db     541 ATCTTTGGCTCTCAAGGTGGCCTTGAGAGGCCAGGGCCAGGGCAATCCTGGAGGTCTGGGG 600

Qy     685 ACTCCGTGGGTCCACGGATACCCCGGAAACTCAGCAGGCAGCTTTGGAATGAATCCTCAG 744
      |||
Db     601 ACTCCGTGGGTCCACGGATACCCCGGAAACTCAGCAGGCAGCTTTGGAATGAATCCTCAG 660

Qy     745 GGAGCTCCCTGGGGTCAAGGAGGCAATGGAGGGCCACCAAACCTTTGGGACCAACACTCAG 804
      |||
Db     661 GGAGCTCCCTGGGGTCAAGGAGGCAATGGAGGGCCACCAAACCTTTGGGACCAACACTCAG 720

Qy     805 GGAGCTGTGGCCAGCCTGGCTATGGTTCAGTGAGAGCCAGCAACCAGAATGAAGGGTGC 864
      |||
Db     721 GGAGCTGTGGCCAGCCTGGCTATGGTTCAGTGAGAGCCAGCAACCAGAATGAAGGGTGC 780

Qy     865 ACGAATCCCCACCATCTGGCTCAGGTGGAGGCTCCAGCAACTCTGGGGGAGGCAGCGGC 924
      |||
Db     781 ACGAATCCCCACCATCTGGCTCAGGTGGAGGCTCCAGCAACTCTGGGGGAGGCAGCGGC 840

Qy     925 TCACAGTCGGGCAGCAGTGGCAGTGGCAGCAATGGTGACAACAACAATGGCAGCAGCAGT 984
      |||
Db     841 TCACAGTCGGGCAGCAGTGGCAGTGGCAGCAATGGTGACAACAACAATGGCAGCAGCAGT 900

Qy     985 GGTGGCAGCAGCAGTGGCAGCAGTGGCGGCAGCAGTGGCGGCAGCAGTGGTGGCAGC 1044
      |||
Db     901 GGTGGCAGCAGCAGTGGCAGCAGTGGCGGCAGCAGTGGCGGCAGCAGTGGTGGCAGC 960
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[illegible]

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Query Match 95.7%; Score 2462.5; DB 3; Length 479;  
 Best Local Similarity 96.0%; Pred. No. 5.9e-152;  
 Matches 460; Conservative 2; Mismatches 14; Indels 3; Gaps 2;

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Qy      1 MKFQGPLACLLALCLGSGEAGPLQSGEESTGTNIGEALGHGLGDALSEG VGKAIGKEAG 60
      |||
Db      1 MKFQGPLACLLALCLGSGEAGPLQSGEESTGTNIGEALGHGLGDALSEG VGKAIGKEAG 60

Qy     61 GAAGSKVSEALGQGTREAVGTGVRQVPFGAADALGNRVGEAAHALGNTGHEIGRQAEDV 120
      |||
Db     61 GAAGSKVSEALGQGTREAVGTGVRQVPFGVADALGNRVGEAAHALGNTGHEIGRQAEDV 120

Qy    121 IRHGADAVRGSWQGVPGHNGAWETSGGHGIFGSGGGLGGQGQGNPGGLGTPWVHGYPGNS 180
      |||
Db    121 IRHGADAVRGSWQGVPGHNGAWETSGGHGIFGSGGGLGGQGQGNPGGLGTPWVHGYPGNS 180

Qy    181 AGSFGMNPQGAPWQGNGGPPNFGTNTQGAQAQPGYGSVRASNQNEGCTNPPPSGSGGG 240
      |||
Db    181 AGSFGMNPQGAPWQGNGGPPNFGTNTQGAQAQPGYGSVRASNQNEGCTNPPPSGSGGG 240

Qy    241 SSNSGGGSGSQSGSSGSGSNGDNNNGSSSGSSSGSSSGSSSGSSGSGSSGNSGSGSRGDS 300
      |||
Db    241 SSNSGGGSGSQSGSSGSGSNGDNNNGSSSGSSSGSSSGSSSGSSGSGSSGNSGSGSRGDS 300

Qy    301 GSESSWGSSTGSSSGNHGGSGGGNGHKPGCE-KPGNEARGSGESGIQ--NSETSPGMFNF 357
      |||
Db    301 GSESSWGSSTGSSSGNHGGSGGGNGHKPGGQGSWSGGGDVGGVNTVNSETSPPGMFNF 360

Qy    358 DTFWKNFKSKLGFINWDAINKNQVPPPSSTRALLYFSRLWEDFKQNTPFLNWKAIIEGADA 417
      |||
Db    361 DTFWKNFKSKLGFINWDAINKNQVPPPSSTRALLYFSRLWEDFKQNTPFLNWKAIIEGADA 420

Qy    418 SSLQKRAGRADQNYNYNQHAYPTAYGGKYSVKTPAKGGVSPSSSASRVQPGLLQWVKFW 476
      |||
Db    421 SSLQKRAGRADQNYNYNQHAYPTAYGGKYSVKTPAKGGVSPSSSASRVQPGLLQWVKFW 479

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Claims 1-4 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Matsui et al. (Genomics, August 2004).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Matsui et al. discloses the gene and amino acid sequences corresponding to instant SEQ ID NOS: 7 and 8. See at least page 384 which discloses the sequences were deposited with Genbank and Figure 2.

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Claims 1-4 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Song et al. (U.S. Patent No 7,326,687).

Song et al. discloses SEQ ID NOS: 2 (2097 nucleotides) and 3 (555 amino acids).

Vectors are disclosed. SEQ ID NO: 2 of Song et al. has 80% identity to instant SEQ ID NO: 7 and SEQ ID NO: 3 of Song et al. has 97% identity to SEQ ID NO: 8. (See sequence listing, claims, and sequence alignment below.) Absent evidence to the contrary and in view of the high structural similarity, the polynucleotide and amino acid sequences of Song et al. would inherently possess the properties recited in claim 1 parts (c) and (d) and claim 2. Evidence that these properties are not possessed by the sequences of Song et al. will be viewed as evidence that the claims are not enabled for the breadth of the polynucleotides encompassed.

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Query Match          80.4%; Score 1593; DB 6; Length 2097;
Best Local Similarity 88.7%; Pred. No. 0;
Matches 1860; Conservative 0; Mismatches 0; Indels 237; Gaps 3;

Qy      78 GAGGAGGACAGAGGAGGGCACAGAGACGCAGAGCAAGGGCGGCAAGGAGGAGACCCTGGT 137
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1  GAGGAGGACAGAGGAGGGCACAGAGACGCAGAGCAAGGGCGGCAAGGAGGAGACCCTGGT 60

Qy     138 GGGAGGAAGACACTCTGGAGAGAGAGGGGGCTGGGCAGAGATGAAGTTCCAGGGGCCCCCT 197
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      61 GGGAGGAAGACACTCTGGAGAGAGAGGGGGCTGGGCAGAGATGAAGTTCCAGGGGCCCCCT 120

Qy     198 GGCCTGCCTCCTGCTGGCCCTCTGCCTGGGCAGTGGGGAGGCTGGCCCCCTGCAGAGCGG 257
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     121 GGCCTGCCTCCTGCTGGCCCTCTGCCTGGGCAGTGGGGAGGCTGGCCCCCTGCAGAGCGG 180

Qy     258 AGAGGAAAGCACTGGGACAAATATTGGGGAGGCCCTTGGACATGGCCTGGGAGACGCCCT 317
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     181 AGAGGAAAGCACTGGGACAAATATTGGGGAGGCCCTTGGACATGGCCTGGGAGACGCCCT 240

Qy     318 GAGCGAAGGGGTGGGAAAGGCCATTGGCAAAGAGGCCGAGGGGAGCTGGCTCTAAAGT 377
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     241 GAGCGAAGGGGTGGGAAAGGCCATTGGCAAAGAGGCCGAGGGGAGCTGGCTCTAAAGT 300

Qy     378 CAGTGAGGCCCTTGGCCAAGGGACCAGAGAAGCAGTTGGCACTGGAGTCAGGCAGGTTCC 437
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     301 CAGTGAGGCCCTTGGCCAAGGGACCAGAGAAGCAGTTGGCACTGGAGTCAGGCAGGTTCC 360

Qy     438 AGGCTTTGGCGCAGCAGATGCTTTGGGCAACAGGGTCGGGGAAGCAGCCCATGCTCTGGG 497
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     361 AGGCTTTGGCGCAGCAGATGCTTTGGGCAACAGGGTCGGGGAAGCAGCCCATGCTCTGGG 420

Qy     498 AAACACTGGGCACGAGATTGGCAGACAGGCAGAAGATGTCATTGACACGGAGCAGATGC 557
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     421 AAACACTGGGCACGAGATTGGCAGACAGGCAGAAGATGTCATTGACACGGAGCAGATGC 480

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Qy	558	TGTCCTCGCGCTCCTGGCAGGGGGTGCCCTGGCCACAATGGTGCTTGGGAAACTTCTGGAGG	617
Db	481	TGTCCTCGCGCTCCTGGCAGGGGGTGCCCTGGCCACAATGGTGCTTGGGAAACTTCTGGAGG	540
Qy	618	CCATGGCATCTTTTGGCTCTCAAGGTGGCCTTGAGAGGCCAGGGCCAGGGCAATCCTGGAGG	677
Db	541	CCATGGCATCTTTTGGCTCTCAAGGTGGCCTTGAGAGGCCAGGGCCAGGGCAATCCTGGAGG	600
Qy	678	TCTGGGGACTCCGTGGGTCCACGGATACCCCGGAAACTCAGCAGGCAGCTTTGGAATGAA	737
Db	601	TCTGGGGACTCCGTGGGTCCACGGATACCCCGGAAACTCAGCAGGCAGCTTTGGAATGAA	660
Qy	738	TCCTCAGGGAGCTCCCTGGGGTCAAGGAGGCAATGGAGGGCCACCAAACCTTTGGGACCAA	797
Db	661	TCCTCAGGGAGCTCCCTGGGGTCAAGGAGGCAATGGAGGGCCACCAAACCTTTGGGACCAA	720
Qy	798	CACTCAGGGAGCTGTGGCCCAGCCTGGCTATGGTTCAGTGAGAGCCAGCAACCAGAATGA	857
Db	721	CACTCAGGGAGCTGTGGCCCAGCCTGGCTATGGTTCAGTGAGAGCCAGCAACCAGAATGA	780
Qy	858	AGGGTGACAGAAATCCCCCACCATCTGGCTCAGGTGGAGGCTCCAGCAACTCTGGGGGAGG	917
Db	781	AGGGTGACAGAAATCCCCCACCATCTGGCTCAGGTGGAGGCTCCAGCAACTCTGGGGGAGG	840
Qy	918	CAGCGGCTCACAGTCTGGGCAGCAGTGGCAGTGGCAGCAATGGTGACAACAACATGGCAG	977
Db	841	CAGCGGCTCACAGTCTGGGCAGCAGTGGCAGTGGCAGCAATGGTGACAACAACATGGCAG	900
Qy	978	CAGCAGTGGTGGCAGCAGCAGTGGCAGCAGCAGTGGCGGCAGCAGTGGCGGCAGCAGTGG	1037
Db	901	CAGCAGTGGTGGCAGCAGCAGTGGCAGCAGCAGTGGCGGCAGCAGTGGCGGCAGCAGTGG	960
Qy	1038	TGGCAGCAGTGGCAACAGTGGTGGCAGCAGAGGTGACAGCGGCAGTGAGTCTCTCTG---	1094
Db	961	TGGCAGCAGTGGCAACAGTGGTGGCAGCAGAGGTGACAGCGGCAGTGAGTCTCTCTGGGG	1020
Qy	1095	-----GGGATCCAGCACCGGCTC	1112
Db	1021	CAGTTCTGGGAATGGTGACCAAGGCAGCTACGGCCGCTCCAGGGATCCAGCACCGGCTC	1080
Qy	1113	CTCTCCGGCAACCACGGTGGGAGCGGCGGAGGAAATGGACATAAACCCGGGTGTGAAAA	1172
Db	1081	CTCTCCGGCAACCACGGTGGGAGCGGCGGAGGAAATGGACATAAACCCGGGTGTGAAAA	1140
Qy	1173	GCCAGGGAATGAAGCCCCGCGGAGCGGGGAATCTGGG-----	1209
Db	1141	GCCAGGGAATGAAGCCCCGCGGAGCGGGGAATCTGGGATTAGGGCTTCAGAGGACAGGG	1200
Qy	1210	-----	1209
Db	1201	AGTTTCCAGCAACATGAGGGAAATAAGCAAAGAGGGCAATCGCCTCCTTGGAGGCTCTGG	1260
Qy	1210	-----	1209
Db	1261	AGACAATTATCGGGGGCAAGGGTCGAGCTGGGGCAGTGGAGGAGGTGACGCTGTTGGTGG	1320
Qy	1210	-----ATTCAGAACTCTGAGACGTCTCTGGGATGTTTAACTTTGACACTTTCTGGAA	1262
Db	1321	AGTCAATATTTCAGAACTCTGAGACGTCTCTGGGATGTTTAACTTTGACACTTTCTGGAA	1380
Qy	1263	GAATTTTAAATCCAAGCTGGGTTTCATCAACTGGGATGCCATAAACAAGAACCAGGTCCC	1322
Db	1381	GAATTTTAAATCCAAGCTGGGTTTCATCAACTGGGATGCCATAAACAAGAACCAGGTCCC	1440
Qy	1323	GCCCCCAGCACCCGAGCCCTCCTCTACTTCAGCCGACTCTGGGAGGATTTCAAACAGAA	1382

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Db 1441 GCCCCCAGCACCCGAGCCCTCCTCTACTTCAGCCGACTCTGGGAGGATTTCAAACAGAA 1500

Qy 1383 CACTCCTTTCTCAACTGGAAAGCAATTATTGAGGGTGCGGACGCGTCATCACTGCAGAA 1442  
|||||

Db 1501 CACTCCTTTCTCAACTGGAAAGCAATTATTGAGGGTGCGGACGCGTCATCACTGCAGAA 1560

Qy 1443 ACGTGCAGGCAGAGCCGATC----- 1462  
|||||

Db 1561 ACGTGCAGGCAGAGCCGATCAGCCGGGTGCAGGATGGCAGGAGTGGCAGCTGTAAC TTC 1620

Qy 1463 --AGAACTACAATTACAACCAGCATGCGTATCCCACTGCCTATGGTGGGAAGTACTCAGT 1520  
|||||

Db 1621 CAAGAACTACAATTACAACCAGCATGCGTATCCCACTGCCTATGGTGGGAAGTACTCAGT 1680

Qy 1521 CAAGACCCCTGCAAAGGGGGGAGTCTCACCTTCTTCCTCGGCTTCCCGGTGCAACCTGG 1580  
|||||

Db 1681 CAAGACCCCTGCAAAGGGGGGAGTCTCACCTTCTTCCTCGGCTTCCCGGTGCAACCTGG 1740

Qy 1581 CCTGCTGCAGTGGGTGAAGTTTTGGTAGGCAATTCTTGCAACCACCACCGAGGCCCGGA 1640  
|||||

Db 1741 CCTGCTGCAGTGGGTGAAGTTTTGGTAGGCAATTCTTGCAACCACCACCGAGGCCCGGA 1800

Qy 1641 AAAGCACTGGTCGTCAGGGAGCTCCTCCCTTGCCCCCAGCCTGTGCCAGCCCTGGCCC 1700  
|||||

Db 1801 AAAGCACTGGTCGTCAGGGAGCTCCTCCCTTGCCCCCAGCCTGTGCCAGCCCTGGCCC 1860

Qy 1701 GGCTGCCACACCTCTGTTTCTAGGCTGGGGACCCAGCTTGTCTCTCCTTGTTCCTTCCC 1760  
|||||

Db 1861 GGCTGCCACACCTCTGTTTCTAGGCTGGGGACCCAGCTTGTCTCTCCTTGTTCCTTCCC 1920

Qy 1761 ACTGCACTGTGGTGCTTTCAGTGGCCACCAGCCTCGTCACATACACCAGCATCTTTCTGTA 1820  
|||||

Db 1921 ACTGCACTGTGGTGCTTTCAGTGGCCACCAGCCTCGTCACATACACCAGCATCTTTCTGTA 1980

Qy 1821 CCTCCTCCCTTTGGTGACCTGAAGTCACTGTGACAGTTCTCCAGGAAGGAGAGCTTCCT 1880  
|||||

Db 1981 CCTCCTCCCTTTGGTGACCTGAAGTCACTGTGACAGTTCTCCAGGAAGGAGAGCTTCCT 2040

Qy 1881 ACTTTTGAGTTTCTCTGTGGAATAAAACATGAATCTTGTTCCTAAAAA AAAAAA 1937  
|||||

Db 2041 ACTTTTGAGTTTCTCTGTGGAATAAAACATGAATCTTGTTCCTAAAAA AAAAAA 2097

Query Match 97.3%; Score 2503.5; DB 3; Length 555;  
Best Local Similarity 85.8%; Pred. No. 1.2e-171;  
Matches 476; Conservative 0; Mismatches 0; Indels 79; Gaps 3;

Qy 1 MKFQGPLACLLALCLGSGEAGPLQSGEESTGTNIGEALGHGLGDALSEG VGKAIGKEAG 60  
|||||

Db 1 MKFQGPLACLLALCLGSGEAGPLQSGEESTGTNIGEALGHGLGDALSEG VGKAIGKEAG 60

Qy 61 GAAGSKVSEALQGQGTREAVGTGVRQVPGFGAADALGNRVGEAAHALGNTGHEIGRQAEDV 120  
|||||

Db 61 GAAGSKVSEALQGQGTREAVGTGVRQVPGFGAADALGNRVGEAAHALGNTGHEIGRQAEDV 120

Qy 121 IRHGADAVRGSWQGVPGHNGAWETSGGHGIFGSQGGGQGGQGNPGGLGTPWVHGYPGNS 180  
|||||

Db 121 IRHGADAVRGSWQGVPGHNGAWETSGGHGIFGSQGGGQGGQGNPGGLGTPWVHGYPGNS 180

Qy 181 AGSFGMNPQGAPWGQGGNGGPPNFGTNTQGAVAQPGYGSVRASNQNEGCTNPPPSGSGGG 240  
|||||

Db 181 AGSFGMNPQGAPWGQGGNGGPPNFGTNTQGAVAQPGYGSVRASNQNEGCTNPPPSGSGGG 240

Qy 241 SSNSGGGSGSQSGSSGSGSNGDNNNGSSSGSSSGSSSGSSSGSSGSGSGNSGSGSRGDS 300  
|||||

Db 241 SSNSGGGSGSQSGSSGSGSNGDNNNGSSSGSSSGSSSGSSSGSSGSGSGNSGSGSRGDS 300

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Qy      301 GSESSW-----GSSTGSSSGNHGGSGGGNGHKPGCEKPGNEARGSGESG- 344
        |||||
Db      301 GSESSWGSSGNGDQGSYGRSQGSSTGSSSGNHGGSGGGNGHKPGCEKPGNEARGSGESGI 360

Qy      345 -----IQNSETSPGMF 355
        |||||
Db      361 QGFRGQGVSSNMREISKEGNRLLGGSGDNYRGQGSSWGSGGDAVGGVNIQNSETSPGMF 420

Qy      356 NFDTFWKNFKSKLGFINWDAINKNQVPPSTRALLYFSRLWEDFKQNTPFLNWKAIIEGA 415
        |||||
Db      421 NFDTFWKNFKSKLGFINWDAINKNQVPPSTRALLYFSRLWEDFKQNTPFLNWKAIIEGA 480

Qy      416 DASSLQKRAGRADQ-----NYYNQHAYPTAYGGKYSVKTPAKGGVSPSSS 461
        |||||
Db      481 DASSLQKRAGRADQPGAGWQEVAAVTSKNYYNQHAYPTAYGGKYSVKTPAKGGVSPSSS 540

Qy      462 ASRVQPGLLQWVKFW 476
        |||||
Db      541 ASRVQPGLLQWVKFW 555

```

Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Strausberg et al. (PNAS, 2002) in view of Genbank Accession No. BC035311 (9/20/02 and 10/12/04 entry revision).

Strausberg et al. discloses a sequence that is identical to instant SEQ ID NO: 7. This sequence was deposited with Genbank. See abstract and sequence alignment of instant SEQ ID NO: 7 with the sequence of BC035311 below. The 10/12/2004 revision of Genbank Accession No. BC035311 identifies this sequence as encoding a dermokine and provides the translated sequence corresponding to SEQ ID NO: 8. The nucleotide sequence in BC035311 was available as of 9/20/02. Applicant is advised that Genbank Accession No. BC035311 references Genbank Accession No. AAH35311. AAH35311 provides the amino acid sequence and was available as of 10/12/04.

Applicant referenced BC035311 in the specification at page 12, line 16.

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Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Query Match		100.0%;	Score 1982;	DB 5;	Length 1982;	
Best Local Similarity		100.0%;	Pred. No. 0;			
Matches 1982;		Conservative	0;	Mismatches	0;	Indels 0; Gaps 0;
Qy	1	TCTGAGAAAGCCCAGGCAGTTGAGGACAGGAGAGAGAAGGCTGCAGACCCAGAGGGAGGGA	60			
Db	1	TCTGAGAAAGCCCAGGCAGTTGAGGACAGGAGAGAGAAGGCTGCAGACCCAGAGGGAGGGA	60			
Qy	61	GGACAGGGAGTCGGAAGGAGGAGGACAGAGGAGGGGCACAGAGACGCAGAGCAAGGGCGGC	120			
Db	61	GGACAGGGAGTCGGAAGGAGGAGGACAGAGGAGGGGCACAGAGACGCAGAGCAAGGGCGGC	120			
Qy	121	AAGGAGGAGACCCCTGGTGGGAGGAAGACACTCTGGAGAGAGAGGGGGCTGGGCAGAGATG	180			
Db	121	AAGGAGGAGACCCCTGGTGGGAGGAAGACACTCTGGAGAGAGAGGGGGCTGGGCAGAGATG	180			
Qy	181	AAGTTCCAGGGGGCCCCTGGCCTGCCTCCTGCTGGCCCTCTGCCTGGGCAGTGGGGAGGCT	240			
Db	181	AAGTTCCAGGGGGCCCCTGGCCTGCCTCCTGCTGGCCCTCTGCCTGGGCAGTGGGGAGGCT	240			
Qy	241	GGCCCCCTGCAGAGCGGAGAGGAAAGCACTGGGACAAATATTGGGGAGGCCCTTGGACAT	300			
Db	241	GGCCCCCTGCAGAGCGGAGAGGAAAGCACTGGGACAAATATTGGGGAGGCCCTTGGACAT	300			
Qy	301	GGCCTGGGAGACGCCCTGAGCGAAGGGGTGGGAAAGGCCATTGGCAAAGAGGCCGAGGG	360			
Db	301	GGCCTGGGAGACGCCCTGAGCGAAGGGGTGGGAAAGGCCATTGGCAAAGAGGCCGAGGG	360			
Qy	361	GCAGCTGGCTCTAAAGTCAGTGAGGCCCTTGGCCAAGGGACCAGAGAAGCAGTTGGCACT	420			
Db	361	GCAGCTGGCTCTAAAGTCAGTGAGGCCCTTGGCCAAGGGACCAGAGAAGCAGTTGGCACT	420			
Qy	421	GGAGTCAGGCAGGTTCCAGGCTTTGGCGCAGCAGATGCTTTGGGCAACAGGGTCGGGGAA	480			
Db	421	GGAGTCAGGCAGGTTCCAGGCTTTGGCGCAGCAGATGCTTTGGGCAACAGGGTCGGGGAA	480			
Qy	481	GCAGCCCATGCTCTGGGAAACACTGGGCACGAGATTGGCAGACAGGCAGAAGATGTCATT	540			
Db	481	GCAGCCCATGCTCTGGGAAACACTGGGCACGAGATTGGCAGACAGGCAGAAGATGTCATT	540			
Qy	541	CGACACGGAGCAGATGCTGTCCGCGGCTCCTGGCAGGGGGTGCCTGGCCACAATGGTGCT	600			
Db	541	CGACACGGAGCAGATGCTGTCCGCGGCTCCTGGCAGGGGGTGCCTGGCCACAATGGTGCT	600			
Qy	601	TGGGAAACTTCTGGAGGCCATGGCATCTTTGGCTCTCAAGGTGGCCTTGGAGGCCAGGGC	660			
Db	601	TGGGAAACTTCTGGAGGCCATGGCATCTTTGGCTCTCAAGGTGGCCTTGGAGGCCAGGGC	660			
Qy	661	CAGGGCAATCCTGGAGGTCTGGGGACTCCGTGGGTCCACGGATACCCCGGAAACTCAGCA	720			
Db	661	CAGGGCAATCCTGGAGGTCTGGGGACTCCGTGGGTCCACGGATACCCCGGAAACTCAGCA	720			
Qy	721	GGCAGCTTTGGAATGAATCCTCAGGGAGCTCCCTGGGGTCAAGGAGGCAATGGAGGGCCA	780			

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Db 721 GGCAGCTTTGGAATGAATCCTCAGGGAGCTCCCTGGGGTCAAGGAGGCAATGGAGGGCCA 780

Qy 781 CCAAACCTTTGGGACCAACACTCAGGGAGCTGTGGCCAGCCTGGCTATGGTTCAGTGAGA 840  
|||||

Db 781 CCAAACCTTTGGGACCAACACTCAGGGAGCTGTGGCCAGCCTGGCTATGGTTCAGTGAGA 840

Qy 841 GCCAGCAACCAGAAATGAAGGGTGCACGAATCCCCACCATCTGGCTCAGGTGGAGGCTCC 900  
|||||

Db 841 GCCAGCAACCAGAAATGAAGGGTGCACGAATCCCCACCATCTGGCTCAGGTGGAGGCTCC 900

Qy 901 AGCAACTCTGGGGGAGGCAGCGGCTCACAGTCGGGCAGCAGTGGCAGTGGCAGCAATGGT 960  
|||||

Db 901 AGCAACTCTGGGGGAGGCAGCGGCTCACAGTCGGGCAGCAGTGGCAGTGGCAGCAATGGT 960

Qy 961 GACAACAACAATGGCAGCAGCAGTGGTGGCAGCAGCAGTGGCAGCAGCAGTGGCGGCAGC 1020  
|||||

Db 961 GACAACAACAATGGCAGCAGCAGTGGTGGCAGCAGCAGTGGCAGCAGCAGTGGCGGCAGC 1020

Qy 1021 AGTGGCGGCAGCAGTGGTGGCAGCAGTGGCAACAGTGGTGGCAGCAGAGGTGACAGCGGC 1080  
|||||

Db 1021 AGTGGCGGCAGCAGTGGTGGCAGCAGTGGCAACAGTGGTGGCAGCAGAGGTGACAGCGGC 1080

Qy 1081 AGTGAGTCTCCTGGGGATCCAGCACCGGCTCCTCCTCCGGCAACCACGGTGGGAGCGGC 1140  
|||||

Db 1081 AGTGAGTCTCCTGGGGATCCAGCACCGGCTCCTCCTCCGGCAACCACGGTGGGAGCGGC 1140

Qy 1141 GGAGGAAATGGACATAAACCCGGGTGTGAAAAGCCAGGGAATGAAGCCCGCGGAGCGGG 1200  
|||||

Db 1141 GGAGGAAATGGACATAAACCCGGGTGTGAAAAGCCAGGGAATGAAGCCCGCGGAGCGGG 1200

Qy 1201 GAATCTGGGATTGAGAACTCTGAGACGTCTCCTGGGATGTTTAACCTTTGACACTTTCTGG 1260  
|||||

Db 1201 GAATCTGGGATTGAGAACTCTGAGACGTCTCCTGGGATGTTTAACCTTTGACACTTTCTGG 1260

Qy 1261 AAGAATTTTAAATCCAAGCTGGGTTTCATCAACTGGGATGCCATAAACAAGAACCAGGTC 1320  
|||||

Db 1261 AAGAATTTTAAATCCAAGCTGGGTTTCATCAACTGGGATGCCATAAACAAGAACCAGGTC 1320

Qy 1321 CCGCCCCCAGCACCCGAGCCCTCCTCTACTTCAGCCGACTCTGGGAGGATTTCAAACAG 1380  
|||||

Db 1321 CCGCCCCCAGCACCCGAGCCCTCCTCTACTTCAGCCGACTCTGGGAGGATTTCAAACAG 1380

Qy 1381 AACACTCCTTTCTCAACTGGAAGCAATTATTGAGGGTGCAGGACGCGTCATCACTGCAG 1440  
|||||

Db 1381 AACACTCCTTTCTCAACTGGAAGCAATTATTGAGGGTGCAGGACGCGTCATCACTGCAG 1440

Qy 1441 AAACGTGCAGGCAGAGCCGATCAGAACTACAATTACAACCAGCATGCGTATCCCACTGCC 1500  
|||||

Db 1441 AAACGTGCAGGCAGAGCCGATCAGAACTACAATTACAACCAGCATGCGTATCCCACTGCC 1500

Qy 1501 TATGGTGGGAAGTACTCAGTCAAGACCCCTGCAAAGGGGGAGTCTCACCTTCTTCCTCG 1560  
|||||

Db 1501 TATGGTGGGAAGTACTCAGTCAAGACCCCTGCAAAGGGGGAGTCTCACCTTCTTCCTCG 1560

Qy 1561 GCTTCCCGGTGCAACCTGGCCTGCTGCAGTGGGTGAAGTTTTGGTAGGCAATTTCTTGC 1620  
|||||

Db 1561 GCTTCCCGGTGCAACCTGGCCTGCTGCAGTGGGTGAAGTTTTGGTAGGCAATTTCTTGC 1620

Qy 1621 AACCACCACCGAGGCCCGAAAAGCACTGGTCGTCAGGAGCTCTCCCTTGCCCCCA 1680  
|||||

Db 1621 AACCACCACCGAGGCCCGAAAAGCACTGGTCGTCAGGAGCTCTCCCTTGCCCCCA 1680

Qy 1681 GCCTGTGCCAGCCCTGGCCCGGTGCCACACCTCTGTTTCTAGGCTGGGGACCCAGCTT 1740  
|||||

Db 1681 GCCTGTGCCAGCCCTGGCCCGGTGCCACACCTCTGTTTCTAGGCTGGGGACCCAGCTT 1740

Qy 1741 GTCTCTCCTTGTCTTCTCCCACTGCACTGTGGTGCTTCAGTGGCCACCAGCCTCGTCACA 1800

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Db      1741  |||||
          GTCTCTCCTTGTCTTCTCCCACTGCACCTGTGGTGCTTCAGTGGCCACCAGCCTCGTCACA 1800
Qy      1801  TACACCAGCATCTTTCTGTACCTCCTCCCTTTGGTGACCTGAAGTCACGTGTGACAGTTCT 1860
          |||||
Db      1801  TACACCAGCATCTTTCTGTACCTCCTCCCTTTGGTGACCTGAAGTCACGTGTGACAGTTCT 1860
Qy      1861  CCAGGAAGGAGGAGCTTCCTACTTTTGAGTTTCTCTGTGGAAATAAAACATGAATCTTGT 1920
          |||||
Db      1861  CCAGGAAGGAGGAGCTTCCTACTTTTGAGTTTCTCTGTGGAAATAAAACATGAATCTTGT 1920
Qy      1921  TTCCCTAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAA 1980
          |||||
Db      1921  TTCCCTAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAA 1980
Qy      1981  AA 1982
          ||
Db      1981  AA 1982

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### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2-4 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 2 is directed to a gene involved in keratinocyte differentiation or proliferation, wherein the gene encodes a secreted protein. The specification does not disclose the nucleotide sequence for any gene. The gene sequence including introns and exons is not disclosed. The specification does not disclose nor contemplate genes corresponding to claim 1. Claim 1, part (a), is directed to degenerate sequences. Claim 1, part (b), is directed to coding regions alone. Claim 1, parts (c) and (d), are directed to non-naturally occurring sequences. None of these would have a naturally occurring or corresponding gene.

Claims 3-4 and 8 as they depend from claim 2 are not enabled for the same reason.

Claims 1 and 3-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claim 1, parts (a) and (b), does not reasonably provide enablement for any other sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 1, parts (c) and (d), are directed to polynucleotides encoding polypeptides with particular properties. The specification does not demonstrate that SEQ ID NO: 7, encoding the polypeptide of SEQ ID NO: 8, has these properties. The polypeptide of SEQ ID NO: 8 is never administered to keratinocytes where these effects are seen. The polynucleotide of SEQ ID NO: 7 is never administered to keratinocytes where these effects are seen. The presence of SEQ ID NO: 7 in a Northern blot does not establish that this sequence is responsible for any particular activity. One of ordinary skill in the art would not have attributed this activity to SEQ ID NO: 7 without further experimentation and characterization. This is not present in the instant specification. Likewise, the specification does not disclose variant sequences (having substitutions, deletions, insertions, and/or additions or that have unspecified sequences that hybridize) that possess these properties. Those regions or amino acids responsible for this activity are not disclosed in the specification. As such, one of ordinary skill in the art would have no direction or guidance as to those polynucleotides to produce that would encode polypeptides having the required properties.

Claims 3-4 as they depend from claim 1 are not enabled for the same reason.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (571)272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/  
Primary Examiner, Art Unit 1647

mpa